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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,048	12/27/2001	Ernst Heinz	0093A000032	5170
26474 7590 08/05/2009 NOVAK DRUCE DELUCA + QUIGG LLP 1300 EYE STREET NW SUITE 1000 WEST TOWER WASHINGTON, DC 20005				
EXAMINER HIBBERT, CATHERINE S				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/019,048

Applicant(s)

HEINZ ET AL.

Examiner

CATHERINE HIBBERT

Art Unit

1636

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 8-10 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8-10 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 May 2009 has been entered.

Claims 4-5, 7, 11-12 and 14-21 are cancelled. Claims 1-3, 6, 8-10 and 13 are pending and under examination in this action.

Response to Amendment

All objections or rejections to cancelled claims 18-21 are moot.

All objections or rejections not repeated herein are withdrawn.

Priority

Foreign priority to the German priority document DE 100 30 976 2, with regard to prior art, is granted to 30 June 2000 with Applicant's submission of 23 April 2009 because the translation of the German Priority (DE 100 30 976.2) document to perfect the foreign priority filing date has now been filed together with a statement that the translation of the certified copy is accurate.

In view of Applicants Amendment to the Claims, filed 23 April 2009, priority for the claimed invention is granted back to the filing date of the 09/347,531 application, filed 7/6/1999.

Claim Objections

Claims 2 and 3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 specifies within Claim 1 that the isolated nucleic acid sequence is derived from a plant or an alga. Claim 3 specifies within Claim 1 that the isolated nucleic acid sequence is derived from *Physcomitrella patens*. *P. patens* is a type of moss which in turn is a type of plant. However, Claims 2 and 3 are not further limiting because the base Claim 1 already specifies the nucleic acid sequence is derived from SEQ ID NO:1, which is a sequence already derived from *Physcomitrella patens* (as described in the 102(a) rejection below).

Additionally, Claim 3 contains a typographical type error in line 1 for the term “a” which should recite “as”.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite in the term "a plant and a yeast comprising at least one isolated nucleic acid sequence" in line 2 because it is unclear how the term "isolated" is meant to be interpreted in the context of how an organism can comprise an "isolated" nucleic acid.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 8-9, and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Girke et al. (Plant J., July, 1998, Vol. 15(1), pp. 39-48, of record in the IDS; and referenced by Score Report result for SEQ ID NO:1 and NO:2).

Currently amended Claims 1-3 and 8 are drawn to a process of preparing an unsaturated fatty acid, which comprises introducing, into an organism being a yeast or plant, at least one isolated nucleic acid sequence encoding a polypeptide having $\Delta 6$ -desaturase activity, selected from the group consisting of:

- (a) A nucleic acid sequence having the sequence shown in SEQ ID NO:1,
- (b) nucleic acid sequences which, as a result of the degeneracy of the genetic code, are derived from the sequence shown in SEQ ID NO:1, and
- (c) a derivative of the nucleic acid sequence shown in SEQ ID NO:1 which encodes the polypeptide with the amino acid sequence shown in SEQ ID NO:2 or a polypeptide having at

least 95% homology at the amino acid level said polypeptide still having Δ 6-desaturase catalytic activity,

and culturing the organism to express the polypeptide and isolating the unsaturated fatty acid from the organism.

Currently amended Claim 9 reads on a transgenic yeast comprising an isolated nucleic acid sequence comprising the sequence shown in SEQ ID NO:1 and Claim 13 is drawn to an isolated nucleic acid comprising SEQ ID NO:1.

Girke et al. teach identification and expression of a Δ 6-desaturase (D6D) from *P. patens* (PPDES6) (e.g., Abstract). At minimum the reference teaches sequences that are derivatives of SEQ ID NO: 1 or encoding polypeptides that share at least 90% sequence identity with sequences shown in SEQ ID NO: 2. (e.g., Figure 1; depicting PPDES6). Furthermore, the reference teaches that the cDNA for PPDES6 is 2012 bp, i.e., SEQ ID NO: 1. (e.g., p. 40, col. 1, last full paragraph). The amino acid sequence disclosed for PPDES6 is the same as that of SEQ ID NO: 2 (Id.).

In addition, the reference teaches expression of PPDES6 in *S. cerevisiae*. (e.g., p. 45, col. 2, ¶ 3; claims 1, 4, 9). Furthermore, expression of PPDES6 in the cells (i.e., cultured cells) produces concentrations of unsaturated fatty acids that are at least 1 or 5%, whereby to measure the concentration of said fatty acids, each would have to be isolated from the yeast cells in the first place. (e.g., p. 45, col. 1, Table 1; claims 1, 7-8).

Regarding Claims 2-3, Girke et al teach PPDES6 is from *P. patens*, a moss, which is a plant.

35 USC 103(a) Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girke et al., as applied to Claims 1-3, 8-9, and 13 above, in further view of Napier et al. (of record).

Girke et al. teach expression of PPDES6 (instant SEQ ID NO:1) in yeast and yeast cells as described above.

The Girke et al. reference does not explicitly teach expression of PPDES6 in plants or oil crop. However, the reference implies that the desaturase, such as PPDES6 isolated from moss, is a good source for producing a wider variety of polyunsaturated fatty acids (UFAs). (e.g., p. 39,

under "Introduction"). In any event, utilization of D6Ds to modify the lipid composition in oilseed crop was a primary focus in the art at the time of invention. For example, Napier et al. discuss utilizing desaturases from different sources for producing a wider variety and beneficial UFAs. (e.g., Abstract; p. 123). More particularly, the reference explicitly notes that the D6D isolated from *P. patens* is another D6D, in the same vein as producing fatty acids in transgenic oilseed crop. (e.g., p. 125, ¶ 1). The primary thrust of Napier et al. is that expression of desaturases in transgenic plants will lead to production of 'designer oil[s]' in said plants so as to meet the demands of the pharmaceutical and chemical industry. (e.g., p. 126, last paragraph).

Therefore, it would have been obvious to utilize the PPDES6 desaturase as taught by Girke in plants or oilseed crop. One would have been motivated to make such transgenic plants and to produce UFAs therein, so as to utilize PPDES6, with the benefit of extending the range of beneficial designer oils or UFAs produced. Furthermore, given the level of skill at the time of invention, there would have been a reasonable expectation of success in producing UFAs in a plant, transformed with PPDES6.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT, whose telephone number is (571)270-3053. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine Hibbert
Examiner/AU1636

/ Christopher S. F. Low /
Supervisory Patent Examiner, Art Unit 1636